भारतीय मानक
Indian Standard

IS 16738 : 2018
[Superseding IS 10141 : 2001 and 10909 : 2001]

खाद्य-पदार्थ तथा औषधियों के संपर्क में आने पर उनके सुरक्षित उपयोग के लिए पॉलीइथाइलीन पॉलीप्रोपायलीन और उनके कोपॉलीमर के संघटकों की निश्चित सूची

Positive List of Constituents for Polypropylene, Polyethylene and their Copolymers for its Safe Use in Contact with Foodstuffs and Pharmaceuticals

ICS 67.250; 83.080.20

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Plastics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

The packaging of foodstuffs and pharmaceuticals is essential for their conservation, transport and handling. It also avoids contamination and maintains hygienic conditions. There is always a possibility of transfer of part of packaging material to the packed material due to intimate contact of each other. Therefore, formulation of the packaging material must be selected to ensure that any such transfer is at a minimum and substances which do migrate from package to the packed material cause no toxic hazard on consumption. These considerations are equally important in case of processing equipment and utensils which come in contact with food, pharmaceuticals, etc.

Plastics are being used on a large scale for packaging of foodstuffs, pharmaceuticals and drinking water. Where direct contact occurs between the packed commodity and the plastics, the high-molecular mass polymer itself does not pose a toxic hazard being inert and essentially insoluble in food. There is, however, a likelihood that migration of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerization solvents and of low molecular mass polymer fraction will occur from the plastics into the packaged material with consequent toxic hazard to the consumers of products packed in plastics.

This standard supersedes IS 10141 : 2001 'Positive list of constituents of polyethylene in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)' and IS 10909 : 2001 'Positive list of constituents of polypropylene and its copolymers in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)'. A large number of constituents are common for polyethylene and polypropylene, thus, the Committee decided to amalgamate IS 10141 and IS 10909. Hence, IS 10141 and IS 10909 stands withdrawn.

In this revision, with the availability of newer, efficient and cost effective additives which can be safely used in contact with foodstuffs, pharmaceuticals and drinking water new additives have been incorporated along with their CAS number, wherever available.

The additives prescribed in the standard are broadly based on information available through published literature of International Regulation and Legislation reports such as British Plastics Federation (BPF), British Industrial Biological Research Association (BIBRA), U.S. FDA Regulations, and European Directives, Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) and REACH (Registration, Evaluation, Authorization and Restriction of Chemicals).

This standard is intended to be used with the series of Indian Standards on plastics for food contact application which is given in Annex A. It is emphasized that these standards need to be used in combination to provide a system of control to the manufacturers of plastics as well as the fabricators of thermoplastic packaging materials to derive maximum benefits. Besides, it may also serve as basis for official agencies to frame suitable legislation to ensure effective safe-guards for the safety and health of consumers where thermoplastics for food contact and pharmaceutical applications are concerned.

Indian Standard

POSITIVE LIST OF CONSTITUENTS FOR POLYPROPYLENE, POLYETHYLENE AND THEIR COPOLYMERS FOR ITS SAFE USE IN CONTACT WITH FOODSTUFFS AND PHARMACEUTICALS

1 SCOPE

1.1 This standard covers positive list of constituents of polyethylene (PE), polypropylene (PP) and their copolymers, manufacturing residues and necessary additives, which may be regarded as safe for use, when properly processed, in contact with foodstuffs, pharmaceuticals and drinking water and when present only in the prescribed limits of concentration.

1.2 It does not purport to establish the suitability of the ingredient singly in a particular foodstuff or pharmaceutical from other than toxicological considerations.

2 REFERENCE

The following standard contains provisions which through reference in this text, constitutes provisions of the standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below:

IS No.	*Title*
9833 : 2014	List of pigments and colorants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)

3 TERMINOLOGY

For the purpose of this standard, the following definitions shall apply.

3.1 Catalyst Residues — The residues of the catalyst system and their products of decomposition, measured by standard assay technique.

3.2 Polyethylene — It consists of basic polymers manufactured by the catalytic polymerization of ethylene as major monomer and α-olefin as co-monomer, such as propylene or 1-butene or 1-hexene or 1-pentene or 1-octene and their various combinations as defined in **3.4** (a) and **3.4** (b).

3.3 Polypropylene — It shall mean,

a) homopolymers of propylene;

b) copolymers of propylene with ethylene and/ or one or more alkene-1-olefines containing C_4 to C_8. The propylene content must constitute not less than 50 percent by mass and monomers with C_4 to C_8 shall constitute not more than 15 percent by mass;

c) blends of homopolymers listed in **3.3** (a) with one or more of the copolymers listed in **3.3** (b);

d) blends of several copolymers listed in **3.3** (b); and

e) blends of polymers listed in **3.3** (a) to **3.3** (d) with poly(isobutylene), butyl rubber, and/or polyethylene and/or olefin basic copolymers such that the propylene content, of the blend is not less than 50 percent by mass and each of the component complies with laid down specification relating to that component.

3.4 Olefin Basic Copolymers

It consist of basic copolymers manufactured by the catalytic copolymerization of,

a) two or more of the 1-alkenes having 2 to 8 carbon atoms. Such olefin basic copolymers contain not less than 96 mass percent of polymer units derived from ethylene and/or propylene, except the following:

   1) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 1-hexene or ethylene and 1-octene shall contain not less than 90 mass percent of polymer units derived from ethylene;
   2) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 1-hexene shall contain not less than 80 but not more than 90 mass percent of polymer units derived from ethylene.
   3) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 1-pentene shall contain not less than 90 mass percent of polymer units derived from ethylene.
   4) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and 1-octene shall contain not less than 50 mass percent of polymer units derived from ethylene.

    5) Olefin basic terpolymers manufactured by the catalytic copolymerization of ethylene, 1-hexene, and/or propylene, and/or 1-butene, shall contain not less than 85 mass percent polymer units derived from ethylene.
    6) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and 1-octene, or ethylene, 1-octene, and either 1-hexene, 1-butene, propylene, or 4-methylpent-1-ene shall contain not less than 80 mass percent of polymer units derived from ethylene.

b) Olefin basic copolymers manufactured by the catalytic copolymerization of propylene and 1-butene shall contain greater than 15 but not greater than 35 mass percent of polymer units derived from 1-butene with the remainder being propylene.
c) Ethylene and butene-1 copolymers (CAS No. 25087-34-7) shall contain not less than 80 mass percent of polymer units derived from ethylene.

3.5 Ethylene and propylene that may contain as a modifier not more than 4.5 mass percent of total polymer units derived by copolymerization with 1,4-hexadiene.

4 REQUIREMENTS

4.1 Basic Resin

Compliance with the list of polypropylene and polyethylene as defined in **3** shall be made in such a way that it contains no ingredients or residues of ingredients used in its manufacture other than those listed in **4.2** and **5**.

4.2 Process Residues

4.2.1 *Polyethylene*

Polyethylene shall contain not more than a total of 0.2 percent by mass of ethylene and other hydrocarbons originating from ethylene and co-monomer feed stock, aldehydes, ketones and organic peroxides or their decomposition products. It shall contain not more than a total of 0.2 percent by mass, measured by standard assay technique, of calcium, aluminium, silicon, titanium, magnesium, chromium (50 ppm, *Max*), sodium carbonate, potassium carbonate, sodium chloride, potassium chloride, other chlorides, cyclic ethers and petroleum hydrocarbon fractions.

4.2.1.1 The residues of the following products shall not exceed 0.3 percent by mass of the finished product:

a) Alkyl, benzene, alkyl-benzene sulphates of sodium, potassium and ammonium, the alkyl group containing C_{10} to C_{20};
b) Alkyl, benzene, alkyl-benzene sulphonates of sodium, potassium and ammonium, the alkyl group containing C_{10} to C_{20};
c) Condensation products of ethylene oxide with monohydric aliphatic alcohols (C_{12} to C_{20}) and their sodium sulphates;
d) Condensation products of ethylene oxide with monobasic aliphatic acids (C_{12} to C_{20}) and their sodium and ammonium sulphates;
e) Condensation products of propylene oxide with monobasic aliphatic acids (C_{12} to C_{20}) and their sodium and ammonium sulphates;
f) Condensation products of ethylene oxide with propylene oxide;
g) Polyvinyl alcohols (viscosity of a 4 percent aqueous solution at 20°C should be at least 4 centipoises); and
h) Magnesium, zirconium, vanadium, ethoxides/alcoxides and C_1 to C_5 alcohols.

4.2.1.2 *Catalyst residues*

The residues of the catalyst system and their products of decomposition, measured by standard assay technique, shall not exceed 0.2 percent by mass of the finished product.

4.2.2 *Polypropylene*

Polypropylene shall contain not more than a total of 0.2 percent by mass of the following when measured by agreed assay technique:

a) Titanium;
b) Aluminium;
c) Hafnium salt;
d) Borate salt;
e) Silica;
f) Electron donors such as phthalates, alkoxysilanes, methyl methacrylate;
g) Sodium carbonate;
h) Potassium carbonate;
j) Sodium chloride;
k) Potassium chloride;
m) Other chlorides;
n) Petroleum hydrocarbon fractions;
p) Magnesium, zirconium, vanadium, benzoates, ethoxides/alkoxides, and C_1 to C_5 alcohols;
q) Organic peroxides;
r) Condensation products of ethylene oxide with monohydric aliphatic alcohols (C_{11} to C_{20}); and
s) Ethoxylated alkyl (C_{12}-C_{18}) amines.

5 AUXILLARY ITEMS FOR WORKING

5.1 The auxiliary items prescribed in Table 1 may be used to maximum level, percentage mass/mass, of the final product in polyethylene, polypropylene and olefin basic copolymers as given in **3**.

5.2 Pigments and Colorants

The pigments and colorants used shall comply with the list and limits prescribed in IS 9833.

Table 1 Auxiliary Items
(*Clause* 5.1)

Sl No.	**Chemical Name**	**CAS No.**	**Maximum Level of Use, Percent Mass/Mass of Final Product**
(1)	(3)	(2)	(4)
1.	Aluminium silicate/kaolin, china clay/calcined kaolin/calcined China clay	1332-58-7; 92704-41-1; 1335-30-4; 66402-68-4	50
2.	Aluminium stearate	637-12-7	3
3.	Barium sulphate	557-051	0.1
4.	Behenic acid	112-85-6	1
5.	Benzene propanoic acid, 3-(1,1-dimethylethyl)-*β*-(3,1 dimethylethyl)-4-hydroxyphenyl-4-hydroxy-*β*-methyl-1,2-ethanediyl ester	32509-66-3	0.5
6.	1,4-Benzenedicarboxylic acid, bis[2-(1,1-dimethylethyl)-6-[[3-(1,1-dimethylethyl)-2-hydroxy-5-methylphenyl]methyl]-4-methylphenyl] ester	57569-40-1	0.075
7.	Bis(2-ethylhexyl) terephthalate	006422-86-2	0.006
8.	*β*-3(4)-Bis(octadecylthio) cyclohexylethane	37625-75-5	0.3
9.	2,6-Bis(1-methylheptadecyl)-*p*-cresol	5012-62-4	0.3
10.	3,9-Bis[2-{3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]undecane	90498-90-1	0.3
11.	5,7-Bis-1,1-dimethylethyl-3-hydroxi-2(3H)-benzofuranone, reaction products with o-xylene	181314-48-7	0.02
12.	Bis(*p*-ethylbenzylidene) sorbitol	79072-96-1	0.3
13.	4,4–Bis(a,a-dimethylbenzyl) diphenyl amine	10081-67-1	0.3[1)]
14.	2,5-bis(5-tert-butyl-2-benzoxazolyl) thiophene	7128-64-5	0.02[1)] 0.015 (for all food types)
15.	Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite with upto 1 percent tri-isopropanolamine	26741-53-7	0.1
16.	2-(3'-tert-Butyl-2'-hydroxy-5'-methyl-phenyl)-5-chloro-benzotriazole having melting range of 137-141ºC (chemical name — bumetrizole)	3896-11-5	0.5
17.	N,N-Bis(2-hydroxyethyl) alkyl (C_{12}-C_{18}) amine	61791-31-9; 71786-60-2; 70955-14-5; 61791-44-4	0.1
18.	Bis(2,2'-methylene-bis-4-methyl-6-tert-butylphenol) terephthalate	119-47-1	0.1
19.	Butylated hydroxyanisole	25013-16-5	0.05
20.	Butylated hydroxytoluene	128-37-0	0.2
21.	Butyl lactate	138-22-7	5
22.	n-Butyl stearate	123-95-5	5
23.	Butyric acid, 3,3-bis(3-tert-butyl-4-hydroxyphenyl) ethylene ester	32509-66-3	0.5
24.	Calcium benzoate	2090-05-3	2
25.	Calcium carbonate	471-34-1; 1317-65-3	25
26.	Calcium bis (monoethyl-3, 5- di-tert- butyl-4 -hydroxybenzyl) phosphonate	65140-91-2	0.2[2)]
27.	Calcium hydroxide	1305-62-0	0.1
28.	Calcium pelargonate	53988-05-9	
29.	Calcium octoate	136-52-7	
30.	Calcium oxide	1305-78-8	
31.	Calcium oxide	1305-78-8	10
32.	Calcium oxide dispersion	1305-78-8	20
33.	Calcium stearate	1592-23-0; 85251-71-4	5

Table 1 — (*Continued*)

(1)	(3)	(2)	(4)
34.	Carbon black	1333-86-4	1. Toluene extractables: 0.1 percent, *Max* 1. UV absorption of cyclohexane extract at 386 nm: <0.02 AU for a 1 cm cell or < 0.1 AU for a 5 cm cell. 1. Benzo (a) pyrene content: 0.25 mg/kg carbon black, *Max* 1. Maximum use level of carbon black in the polymer: 2.5 percent (*w/w*).
35.	Cyclic neopentanetetrayl bis(octadecyl phosphite)		
36.	4,4'-Cyclohexylidene bis(2-cyclohexyl phenol)		
37.	Citric acid monohydrate	5949-29-1	0.01
38.	Dibenzylidene sorbitol	32647-67-9	0.25
39.	12H-Dibenzo[d,g][1,3,2] dioxaphosphacin,2,4,8,10-tetrakis (1,1-dimethylethyl)-6-hydroxy-,6-oxide, lithium salt	85209-93-4	0.25
40.	2,6 Di-tert-butyl-4-ethylphenol	4130-42-1	0.1 2)
41.	2,6-Di (*α*-methyl benzyl)-4-methylphenol	3806-34-6	
42.	3,5-Di-tert-butyl-4-hydroxy hydrocinnamic acid trimester with 1,3,5-tris(2-hydroxy-ethyl)-5-triazine-2,4,6-(1H,3H,5H) trione		
43.	Di-tert-butylphenyl phosphonite condensation with biphenyl	119345-01-6	0.1 1. Phosphor content 5.4-5.9 percent 1. Acid value of max. 10 mg KOH/g, 1. Melt range of 85-110ºC
44.	2,4-Di-tert-butylphenyl-3,5-di-tert-butyl-4-hydroxybenzoate	4221-80-1	0.5 1)
45.	Dilauryl thiodipropionate	123-28-4	1.0
46.	2,4-dimethoxy-6-(l-pyrenyl)-8-triazine dimethyl dibenzylidene sorbitol		
47.	Distearyl thiodipropionate	693-36-7	1.0
48.	2,4-Dimethoxy-6-(-1-pyrenyl)-s-triazine	3271-22-5	
49.	Dimethyl succinate 2-(4-hyroxy 2,2,6,6-tetramethyl-1-piperidyl) ethanol polycondensate	65447-77-0	
50.	Dimethyl succinate polymer with 4-hydroxy-2,2,6,6-tetramethyl-1-piperidineethanol	65447-77-0	0.3
51.	Distearyl pentaerythritol diphosphite	3806-34-6	0.3
52.	2,4-Di-*tert*-pentyl-6,1-(3,5-di-tert-pentyl-2-hydroxy phenyl) ethyl phenyl acrylate	123968-25-2	0.2
53.	N,N'-Distearoyl ethylenediamine	110-30-5	5
54.	n-Dodecanol	112-53-8	2
55.	Calcium magnesium dicarbonate	7000-29-5	2.0 3)
56.	Di-tert-butylphenyl phosphonite condensation product with bisphenol	119345-01-6	0.1 1. Phosphor content 5.4-5.9 percent; 1. Acid value of max. 10 mg KOH/g; 2. Melt range of 85-110ºC.
57.	2-Ethoxy-5-tert-butyl-2'-ethyl-oxalic acid bis anilide (85-90 percent) and 2-ethoxy-5-tertbutyl-2'-ethyl-4-tertbutyl-oxalic acid-bis anilide		
58.	Erucamide/ 13-Docosenamide	112-84-5	2
59.	2,2'-Ethylidene bis(4,6-di-tert-butylphenol)	35958-30-6	0.05
60.	Fumaric acid	110-17-8	2.5
61.	Glycerine	56-81-5	3.5
62.	Glyceryl oleate	25496-72-4; 111-03-5	
63.	Glyceryl stearate	31566-31-1	3.0
64.	Glyceryl ricinoleate	5086-52-52	3.0
65.	Glyceryl triacetate	102-76-1	30
66.	Heavy liquid paraffin	85535-86-0	10
67.	Hexadecyl-3,5-di-tert-butyl-4-hydroxy benzoate	67845-93-6	0.5
68.	Hydrotalcite (basic magnesium aluminium carbonate hydrate)/ aluminium magnesium carbonate hydroxide	11097-59-9	0.3

Table 1 — (*Continued*)

(1)	(3)	(2)	(4)
69.	Sodium di(*p*-tert-butylphenyl) phosphate	10491-31-3	
70.	2 2'-Hydroxy-3'-tert-butyl-5'-methylphenyl-5-chloro-benzotriazole (melt range of 126-132 °C)	3896-11-5	0.5
71.	2-Hydroxy-4-*n*-octoxy-benzophenone	1843-05-6	3.5
72.	Lauric diethanolamide	120-40-1	0.5
73.	Lithium benzoate	553-54-8	0.4
74.	*n*-Lauroyl sarcosine	97-78-9	0.4[4)]
75.	Magnesium benzoate	553-70-8	2
76.	Magnesium oxide	1309-48-4	0.05
77.	Magnesium stearate	557-04-0	1.0
78.	Maleic anhydride grafted polyethylene		10.0
79.	Mannitol	87-78-5; 69-65-8	2.5
80.	2,2'-Methylene bis(4-methyl-6-tert-butylphenol)	119-47-1	0.01
81.	2,2'-Methylenebis 6-(1-methylcyclo-hexyl)-*p*-cresol	77-62-3	0.2
82.	7-(2H-naphtho[1,2-d]triazol-2-yl)-3-phenyl-2-benzopyrone	3333-62-8	0.1
83.	Oleamide	301-02-0	0.5
84.	Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	0.25
85.	Oxidised bis(hydrogenated tallow alkyl) amine	143925-92-2	0.1
86.	O,O-di-*n*-Octadecyl 3,5 di-tert-butyl-4-hydroxybenzyl Phosphonate	3135-18-0	0.5
87.	2,2'-Oxamidobis[ethyl-3-(3.5-di-*tert*-butylhydroxyphenyl) propionate]	70331-94-1	0.5
88.	Phosphoric acid, cyclic butylethyl propanediol, 2,4,6-tri-tert-butylphenyl ester	161717-32-4	0.2
89.	Phosphoric acid, cyclic neopentane tetrayl bis(2,4-di-tert-butylphenyl) ester	26741-53-7	0.1
90.	Pentaerythritol	126-58-9	3
91.	Polyvinyl cyclohexane	25498-06-0	0.1
92.	Poly(6-morpholino-s-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino)] hexamethylene-[(2,2,6,6-tetramethyl-4- piperidyl)imino)] polyisobutylene	82451-48-7	0.3
93.	Polydimethyl siloxane	63148-62-9	5
94.	Polyoxyethylene (20) sorbitan monolaurate	9005-64-5	3
95.	Polyoxyethylene (20) sorbitan monooleate	9005-65-6	3
96.	Polyoxyethylene (20) sorbitan monopalmitate	9005-66-7	3
97.	Polyoxyethylene (20) sorbitan monostearate/ Ethoxylated (20) sorbitan monostearate	9005-67-8	3
98.	Polyoxyethylene (20) sorbitan tristearate	9005-71-4	3
99.	Poly[6-[(1,1,3,3-tetramethylbutyl)-amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene-(2,2,6,6-tetramethyl-4-piperidyl)imino]	71878-19-8; 70624-18-9	0.3
100.	Polypropylene glycol	25322-69-4	0.5
101.	Silicon dioxide/ flux calcined diatomaceous earth/ diatomite, diatomaceous earth, DE, kieslgu/ calcined diatomaceous earth/ diatomite/ diatomaceous earth/ synthetic amorphous silica	7631-86-9; 14464-46-1; 14808-60-7; 68855-54-9; 61790-53-2; 91053-39-3; 63231-67-4; 112945-52-5	No specific limit
102.	Sodium benzoate	532-32-1	No specific limit
103.	Sodium calcium aluminosilicate hydrate	1344-01-0	No specific limit
104.	Sorbitan monolaurate	1338-39-2	3
105.	Sorbitan monooleate	1338-43-8	3
106.	Sorbitan monopalmitate	26266-57-9	3
107.	Sorbitan monostearate	1338-41-6	3
108.	Sorbitan trioleate	26266-58-0	3
109.	Sorbitan tristearate	026658-19-5	3

Table 1 — (*Continued*)

(1)	(3)	(2)	(4)
110.	Sodium di(*p*-tert-butylphenyl) phosphate	10491-31-3	
111.	Sodium 2,2'-methylenebis-(4,6-di-tert-butylphenyl) phosphate	85209-91-2	0.3
112.	Stearic/ palmitic acid	57-11-4; 57-10-3	5
113.	Styrenated *p*-cresol	68610-51-5	0.2[5)]
114.	Talc	14807-96-6	40
115.	Terpolymer of ethylene, propylene and 1,4-hexadiene	26337-35-9	25
116.	Tetrakis-(2,4-di-tert-butylphenyl)-4,4' biphenylene diphosphonite	38613-77-3; 119345-01-6	0.3
117.	Tetrakis[methylene-3-(3',5'-di-tert-butyl-4'-hydroxyphenyl)propionate] methane	6683-19-8	0.5
118.	4,4'-Thio-bis(6-tert-butyl-*m*-cresol)	96-69-5	0.25
119.	Thiodipropionic acid	123-28-4	0.1
120.	Titanium dioxide	13463-67-7	20
121.	*α*-Tocopherol	10191-41-0	No specific limit
122.	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxy benzyl) benzene	1709-70-2	1
123.	Tri(mixed mono and dinonyl phenyl) phosphite, Tris(nonylphenyl) phosphite	26523-78-4	1
124.	1,3,5-tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	40601-76-1	0.25
125.	1,3,5-tris(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl) hexahydro-s-triazine	26175-70-2	0.1
126.	l,3,5-Tris(3,5-di-tert-butyl-4-hydroxy-benzyl)-s-triazine-2,4,6(1H,3H,5H)-trione	27676-62-6	0.1
127.	2-[2,4,8,10-tetrakis(l,1-dimethyl)benzo[d,f][1,3,2]-dioxaphosphepin-6-yl]-N,N-bis [2][2,4,8,10 – tetrakis (1,1-dimethylethyl)dibenzo[d,f][1,3,2] dioxaphosphepin-6-yl]oxy]ethyl]ethanamine	80410-33-9	0.075
128.	Tris (2,4, di-tert-butylphenyl)phosphite	31570-04-4	0.25
129.	Trisodium phosphate	10101-89-0; 7601-54-9	0.1
130.	1,1,3-Tris(2-methy1-4-hydroxy-5-tert -butylphenyl) butane	1843-03-4	0.25 [1)]
131.	Vinylidene fluoride/ hexafluoropropylene copolymer	9011-17-0	0.2
132.	White soft paraffin	72968-50-4	25
133.	Zinc acetate	557-34-6	0.2
134.	Zinc benzoate	553-72-0	2
135.	Zinc di-(2-ethylhexanoate)	136-53-8	1.5
136.	Zinc oxide	1314-13-2	No specific limit
137.	Zinc stearate fatty acids, C_{16}-C_{18} zinc salts	557-05-1; 91051-01-3	3
138.	Aluminum 2,2'-Methylenebis-(4,6-di-tert-butyl-phenyl) phosphate.	151841-65-5	0.25[5)]
139.	Polymer of 2,2,4,4-tetramethyl-7-oxa-3,20-diaza-dispiro [5,1,11,2]-heneicosan-21-one and epichlorohydrin	202483-55-4	0.3
140.	1,3:2,4-Bis(3,4-dimethylbenzylidene) sorbitol	135861-56-2	0.4
141.	3,9-Bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5,5]undecane which shall contain not more than 2 percent by mass of tri-isopropanolamine (CAS No. 122-20-3)	154862-43-8	0.15
142.	Bis(4-propylbenzylidene) propyl sorbitol	882073-43-0	0.5
143.	Feldspar	68476-25-5	50
144.	Xanthan gum	11138-66-2	No specific limit
145.	Calcium aluminum silicate	1327-39-5	50
146.	Potassium aluminum silicate	12251-44-4; 1327-44-2	50
147.	Sodium aluminum silicate	1344-00-9; 73987-94-7	50

Table 1 — (*Continued*)

(1)	(3)	(2)	(4)
148.	Hafnium and borate salt	13499-05-3; 1330-43-4	
149.	Cis-Endo-bicuclo-(2,2,1)-heptane-2,3-dicarboxylic acid, disodium salt	351870-33-2	0.25
150.	1,2-Cyclohexane dicarboxylic acid, calcium salt	491589-22-1	0.25
151.	CI Pigment Blue.	57455-37-5	
152.	D-Glucitol, 1,3:2,4-bis-O-[(4-methylphenyl) methylene]/ D-Glucitol, 1,3:2,4-bis-O-[(4-methylphenyl) methylene]/ D-Glucitol, bis-O-[(4-methylphenyl) methylene]/ 1,3:2,4-bis-O-(4-methylbenzylidene)-D-sorbitol/ Bis(*p*-methylbenzylidene) sorbitol/ 1,3:2,4-Di(methylbenzylidene)-sorbitol	81541-12-0; 54686-97-4	
153.	D-Glucitol, 1,2,3,4-bis-O-[(3,4-dimethylphenyl) methylene]	135861-56-2	0.4
154.	Silane, dichlorodimethyl- reaction products with silica	68611-44-9	0.02
155.	Nonitol, 1,2,3-trideoxy-4,6:5,7-bis-O-[(4-propylphenyl)methylene]	882073-43-0	0.5 (Specific migration limit including the sum of its hydrolysis products)
156.	Other glyceryl esters namely, laurate and behenate	27215-38-9; 77538-19-3	
157.	1,2-Bis (3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)-hydrazine	32687-78-8	0.12
158.	Polyethylene glycol	25322-68-3	0.2
159.	Stearamide	124-26-5	0.2
160.	Polyvinylidene fluoride	24937-79-9	1
161.	2-(4,6-Bis-(2,4-dimethylphenyl)-1,3,5-triazin-2-yl)-5-(octyloxy)-phenol	2725-22-6	0.3
162.	C_{11}-C_{14} Isoalcohols, C_{13}-rich, ethoxylated	78330-21-9	No specific limit
163.	C_{11}-C_{15} Straight chain secondary alcohols, 7-20 moles ethoxylated	68131-40-8	1.8 mg/kg (specific migration limit)
164.	2,5-Dimethyl-2,5-di(*tert*-butylperoxy)hexane	78-63-7	<0.01 residual Tertiary butyl alcohol
165.	White mineral oil/ petroleum oil/ paraffin oil	8042-47-5	0.14
166.	Amines, bis(hydrogenated rape-oil alkyl) methyl, N-oxides	204933-93-7	0.1
167.	Ethylene bisoleamde (EBO)	110-31-6	5
168.	Poly(ethylene propylene) glycol	9003-11-6; 106392-12-5	0.5
169.	Polyethylene glycol	25322-68-3	
170.	N,N'-Ethane-1,2-diylbisoleamide	110-31-6	
171.	C_{11}- C_{14} Isoalcohols, C_{13}-rich, ethoxylated	78330-21-9	1.8 mg/kg (Specific migration limit for food contact application)
172.	Polyethylene powder	9002 88-4	
173.	1,2-Bis (3,5-di-tert-buty l-4-hydroxyhydrocinnamoyl)-hydrazine	32687-78-8	0.12
174.	Sodium stearate	822-16-2	No specific limit
175.	Glycerides, C_{14}-C_{18} mono- and di-Glycerides, tallow mono-, di- and tri-, hydrogenated	67701-33-1; 68308-54-3	No specific limit
176.	Mineral oil	8042-47-5	0.14
177.	Petrolatum/ vaseline	8009-03-8	No specific limit
178.	N,N?Ethylenebisstearamide	110-30-5	No specific limit
179.	N,N-Bis(2-hydroxyethyl)alkyl (C_{13}-C_{15}) amine)	70955-14-5	
180.	Glyceryl distearate	1323-83-7	
181.	Ultramarine pigment violet 15	12769-96-9	
182.	2,2?(2,5-Thiophenediyl)-bis (5-tert-butylbenzoxazole)	7128-64-5	0.015
183.	Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl) phenyl triesters	939402-02-5	2000 ppm

Table 1 — (*Concluded*)

(1)	(3)	(2)	(4)
184.	2,5-Dimethyl-2,5-di (tert-butyl peroxy) hexane	78-63-7	1. 5100 ppm 1. For use as an initiator in the production of propylene homopolymer complying with 177.1520(c), **1.1** and olefin copolymers complying with 177.1520(c), **3.1** and **3.2** and containing not less than 75 mass percent of polymer units derived from propylene, provided that the maximum concentration of tert-Butyl Alcohol in polymer does not exceed 100 ppm, as determined by a method 'Determination of tert-Butyl Alcohol in Polypropylene' which is incorporated by reference. Copies are available from the Cetre for Food Safety and Applied Nutrition (HFS-200).

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[1] Non fatty food only.

[2] Maximum thickness of article in contact with foodstuff and pharmaceuticals shall be 0.025 inch (0.063 5 cm).

[3] Non acidic food only.

[4] Film only.

[5] Not for food contact above 65°C.

ANNEX A

(*Foreword*)

LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE IN CONTACT WITH FOODSTUFFS AND PHARMACEUTICALS

IS No.	*Title*
9833 : 2014	List of pigments and colorants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
9845 : 1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis (*second revision*)
10141 : 2001	Positive list of constituents of polyethylene in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
10142 : 1999	Polystyrene (crystal and high impact) for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification (*first revision*)
10146 : 1982	Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10148 : 1982	Positive list of constituents of polyvinyl chloride and its copolymers for safe use in contact with foodstuffs, pharmaceuticals and drinking water
10149 : 1982	Positive list of constituent of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water
10151 : 1982	Polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
10910 : 1984	Specification for polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11434 : 1985	Ionomer resins for its safe use in contact with foodstuffs, pharmaceutical and drinking water

IS No.	*Title*
11435 : 1985	Positive list of constituents of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11704 : 1986	Ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
11705 : 1986	Positive list of constituents of ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
12229 : 1987	Positive list of constituents of poly alkylene terephthalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceutical and drinking water
12247 : 1988	Nylon-6 polymer for its safe use in contact with foodstuffs pharmaceuticals and drinking water
12248 : 1988	Positive list of constituents of nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
12252 : 1987	Polyalkylene terephthalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
13449 : 1992	Positive list of constituents of ethylene vinyl acetate (EVA) copolymers in contact with foodstuffs, pharmaceuticals and drinking water
13576 : 1992	Ethylene menthacrylic acid (EMAA) copolymers and terpolymers for their safe use contact with foodstuffs, pharmaceuticals and drinking water
13577 : 1992	Positive list of constituents of ethylene methacrylic acid (EMAA) copolymers and terpolymers in contact with foodstuffs, pharmaceuticals and drinking water
13601 : 1993	Ethylene vinyl acetate (EVA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
14971 : 2001	Polycarbonate resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
14972 : 2001	Positive list of constituents of polycarbonate resins in contact with foodstuffs, pharmaceuticals and drinking water
14996 : 2001	Positive list of constituents of modified poly(phenylene oxide) (PPO) in contact with foodstuffs, pharmaceuticals and drinking water
14997 : 2001	Modified poly (Phenylene oxide) (PPO) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
14998 : 2001	Positive list of constituents of melamine-formaldehyde resins in contact with foodstuffs, pharmaceuticals and drinking water
14999 : 2001	Melamine-formaldehyde moulding materials for its safe use in contact with foodstuffs, pharmaceuticals and drinking water

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